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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/585,662  | 02/06/2008  | Leendert Taal        | 5100-000041/US      | 7931             |
| 30593   | 7590        | 10/13/2009           | EXAMINER            |                  |
| HARNESS, DICKEY & PIERCE, P.L.C.<br>P.O. BOX 8910<br>RESTON, VA 20195 |             |                      |                     | MI, QIUWEN       |
| ART UNIT  |             | PAPER NUMBER         |                     |                  |
| 1655  |             |                      |                     |                  |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

|                              |                        |                     |  |
|------------------------------|------------------------|---------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |  |
|                              | 10/585,662             | TAAL ET AL.         |  |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |  |
|                              | QIUWEN MI              | 1655                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 14 August 2009.

2a) This action is **FINAL**.                    2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-7 and 10 is/are pending in the application.

4a) Of the above claim(s) 10 is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 1-7 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

|  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ .                                    |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ .  | 6) <input type="checkbox"/> Other: _____ .                        |

## **DETAILED ACTION**

Applicant's amendment in the reply filed on 8/14/09 is acknowledged. Claims 8 and 9 are cancelled. Claims 1-7, and 10 are pending. Claim 10 is withdrawn. **Claims 1-7 are examined on the merits.**

Any rejection that is not reiterated is hereby withdrawn.

### **Claim Rejections –35 USC § 103**

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-7 remain rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Flynn (The herbal management of stress, Australian journal of medical herbalism, 1996: 8 (1): 15-18), Widy-Tyszkiewicz et al (A randomized double blind study of sedative effects of phytotherapeutic containing valerian, hops, balm and motherwort versus placebo, Herba polonica, (1997) Vol. 43, No. 2, pp. 154-159), Singh et al (Therapeutic potential of Kava in the treatment of anxiety disorders, CNS drugs 2002: 16 (11): 731-743), McClung (US 6579543) and Sandoval (Cat's claw (Uncaria tomentosa) protects against oxidative stress and indomethacin-induced intestinal inflammation, Gastroenterology, 1997; 112 (4 suppl.): A1081).

This rejection is maintained for reasons of record set forth in the Office Action mailed out on 4/30/09, repeated below. Applicants' arguments filed have been fully considered but they are not deemed to be persuasive.

Flynn teaches herbs offer an extremely successful way to manage both physiological and psychological response to stress. *Avena sativa* is great to use in cases of ongoing stress to feed and restore the nervous system (page 16, 1<sup>st</sup> column, 2<sup>nd</sup> paragraph). Flynn also teaches *Avena* feeds the nervous system in an active sense as a nutrient, and is therefore useful as a long term measure in any stress condition (page 17, 1<sup>st</sup> column, 3<sup>rd</sup> paragraph) (thus the third composition). *Glycyrrhiza glabra* has wide application to stress, both in adrenal support and for stress-induced problems (page 16, 1<sup>st</sup> column, 4<sup>th</sup> paragraph) (thus the fifth composition). *Eleutherococcus senticosus* studies have shown it to increase both mental and physical stamina during periods of stress by up to 70%, and it also counters the debility and stress of chronic disease and surgery (page 16, 2nd column, last paragraph) (thus the second composition).

Flynn does not teach using *Avena sativa*, *Glycyrrhiza glabra*, and *Eleutherococcus senticosus* in one kit, neither does Flynn teach the incorporation of *Melissa officinalis*, *Piper methysticum*, *Ballota nigra*, or *Uncaria tomentosa* into the kit; neither does Flynn teach the pharmaceutical form of tablet or capsule.

Widy-Tyszkiewicz et al teach a commercially available anti-stress tablets (thus at least one composition is in the form of a capsule or tablet) containing 50 mg of balm leaves (*Melissa officinalis*) etc (page 154, 2<sup>nd</sup> paragraph from the bottom). It is deemed that a tablet contains a pharmaceutically acceptable carrier such as a binding agent.

Singh et al teach kava (*Piper methysticum*) has been shown to be effective in mild to moderate cases of anxiety. Its biological activity, due to a mixture of compounds called kavalactone, are reported to include antistress properties etc (see Abstract) (thus a fourth composition in claim 3).

McClung teaches an antidepressant/anti-anxiety/anti-stress compound is selected from the group consisting of black horehound etc (the same as *Ballota nigra*) (col 3, lines 45-55),

Sandoval teaches *Uncaria tomentosa* protects cells against oxidative stress (see Abstract) (thus sixth composition).

"It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose ...[T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) (citations omitted).

In the instant case, all of the above-listed ingredients were known for anti-stress activity. Thus, one of ordinary skill in the art would have had a reasonable expectation that the combination of these compounds would have been additively beneficial for anti-stress activity.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the instant ingredients for their known benefit since each is well known in the art for anti-stress activity. This rejection is based on the well established proposition of patent law that no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients, *In re Sussman*, 136 F.2d 715, 718, 58 USPQ 262, 264 (CCPA 1943).

It has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. The differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. “[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.” In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). (Claimed process which was performed at a temperature between 40°C and 80°C and an acid concentration between 25% and 70% was held to be prima facie obvious over a reference process which differed from the claims only in that the reference process was performed at a temperature of 100°C and an acid concentration of 10%.); see also Peterson, 315 F.3d at 1330, 65 USPQ2d at 1382 (“The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages.”); In re Hoeschle, 406 F.2d 1403, 160 USPQ 809 (CCPA 1969) (Claimed elastomeric polyurethanes which fell within the broad scope of the references were held to be unpatentable thereover because, among other reasons, there was no evidence of the criticality of the claimed ranges of molecular weight or molar proportions.). For more recent cases applying this principle, see Merck & Co. Inc. v. Biocraft Laboratories Inc., 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989); In re Kulling, 897 F.2d 1147, 14 USPQ2d 1056 (Fed. Cir. 1990); and In re Geisler, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997). see MPEP §

2144.05 part II A. Although the prior art did not specifically disclose the amounts of each constituent, it would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to determine all operable and optimal concentrations of components because concentrations of the claimed components are art-recognized result effective variables because they have anti-stress activity, which would have been routinely determined and optimized in the pharmaceutical art.

Accordingly, the instant claims, in the range of proportions where no unexpected results are observed, would have been obvious to one of ordinary skill having the above cited references before him.

Therefore, it would have been *prima facie* obvious for one of ordinary skill in the art at the time the invention was made to combine the inventions of Flynn, Widy-Tyszkiewicz et al, Singh et al, McClung, and Sandoval since all of them teach compositions for anti-stress activity individually in the art. Since all the compositions yielded beneficial results for anti-stress activity, one of ordinary skill in the art would have been motivated to make the modifications to combine the references together. Regarding the limitation to the amount of the composition in the kit, the result-effective adjustment in conventional working parameters is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

The intended use of the composition was analyzed for patentable weight. It is deemed that the preamble 'breathes life' into the claims in that the prior art product must not be precluded for use to treat lupus, multiple sclerosis, rheumatoid arthritis, rheumatism, osteoporosis, asthma in

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humans or tale and mane eczema in horses. It is deemed that the composition disclosed by the cited reference is not precluded for carrying out the intended function of the claims.

From the teachings of the references, it is apparent that one of the ordinary skills in the art would have had a reasonable expectation of success in producing the claimed invention.

Thus, the invention as a whole is *prima facie* obvious over the references, especially in the absence of evidence to the contrary.

Applicant summarized what each reference teaches and argues that “In view of the above-mentioned differences between treating lupus, tail and mane eczema as recited in claims 1 and 3 and treating stress as allegedly taught in the prior art, and the fact that neither Flylm, Widy-Tyszkiewicz, Singh, McClung or Sandoval discloses that the individual components can be used to treat lupus and/or tail and mane eczema, one skilled in the art would not have been motivated to combine Flylm, Widy-Tyszkiewicz, Singh, McClung and Sandoval to render claims 1 and 3 obvious” (page 14, 3<sup>rd</sup> paragraph).

It is true that none of the references teach the intended use of the claims and it is true that treating stress or anti-stress is different from the claimed treatment of lupus, multiple sclerosis, rheumatoid arthritis, rheumatism, osteoporosis, and asthma in humans or tail and mane eczema in horses. However, these are product claims, not method claims. As indicated previously, the intended use of the composition was analyzed for patentable weight. It is deemed that the preamble ‘breathes life’ into the claims in that the prior art product must not be precluded for use to treat lupus, multiple sclerosis, rheumatoid arthritis, rheumatism, osteoporosis, asthma in

humans or tale and mane eczema in horses. It is deemed that the composition disclosed by the cited reference is not precluded for carrying out the intended function of the claims.

Applicant argues that "Irrespective of the alleged correlation between stress and lupus and tail and/or mane eczema, not all of the individual components of Flylm, Widy- Tyszkiewicz, Singh, McClung and Sandoval are used for treatment of stress. In addition, there is a distinction between stress in the sense of mental stress experienced by people and oxidative stress experienced on a cellular level by macrophages as mentioned by Sandoval. In contrast, *Piper methysticum* is disclosed for having remedial properties against anxiety disorders while leaves of *Melissa officinalis* are disclosed for treatment of insomnia. Therefore, Applicants respectfully submit that the oxidative protection provided by *Uncaria tomentosa* in Tomatosa cannot be "useful for the same purpose" as the anti-stress activity relating to mental stress conferred by other components in the other cited art documents, nor is it clear that *Melissa officinalis* used in Widy-Tyszkiewicz has any purpose in treating stress" (page 14, last paragraph bridging page 15).

This is not found persuasive. First of all, Widy-Tyszkiewicz et al explicitly teach a commercially available anti-stress tablets containing 50 mg of balm leaves (*Melissa officinalis*), thus it would have been obvious for one of the ordinary skill in the art to use *Melissa officinalis* as an anti-stress medicine. Secondly, since Singh et al teach a mixture of compounds called kavalactonse in *Piper methysticum* are reported to include antistress properties, it would have been obvious for one of the ordinary skill in the art to use *Piper methysticum* as an anti-stress medicine. Thirdly, since Sandoval teaches *Uncaria tomentosa* protects cells against oxidative

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stress in vitro, it would have been obvious for one of the ordinary skill in the art to try to use *Uncaria tomentosa* as an anti-stress medicine *in vivo*.

Applicant's arguments have been fully considered but they are not persuasive, and therefore the rejections in the record are maintained.

### **Conclusion**

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Qiuwen Mi whose telephone number is 571-272-5984. The examiner can normally be reached on 8 to 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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QM

/Michele Flood/

Primary Examiner, Art Unit 1655